

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:) Attorney Docket No.: 978150.2/GEI-P0001
)
Soerensen et al.) Confirmation No: 4692
)
Application No.: 10/725,039) Group Art Unit: 1761
)
Filed: December 2, 2003) Examiner: Anthony J. Weier
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For: APPARATUS AND METHOD FOR)
HYDROLYSIS OF A PROTEIN)
CONTAINING RAW MATERIAL AND)
APPLICATION OF THE RESULTING)
HYDROLYSIS PRODUCTS)

DECLARATION UNDER 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Dr. Bomi Framroze, hereby declare as follows:

1. I am working as a paid consultant for Green Earth Industries LLP.
2. I am also the Chief Executive Officer at Opus Organics Pvt. Ltd., whose principal place of business is located at, 3 Shree Sadan, 4/A Carmichael Rd., Mumbai 400, 026, India.
3. I received a PhD in Organic Chemistry from Bryn Mawr College in 1986. I have been working in the field of organic chemistry for 21 year and have 16 years of working experience in process chemistry and protein processing. I started working as a research scientist at the Agricultural Research Division in American Cyanamid in 1987 and I also served as Associate Director for American Cyanamid until 1996. I worked as Executive Director, Technical at Gharda Chemicals Ltd, Mumbai, India, from 1996 to 2000. I have been working as the Chief Executive Officer at Opus Organic Pvt. Ltd. since 2003.

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4. I have reviewed US Patent Application, Serial No. 10/725,039, published as US Patent Application Publication No. US 2005/0037109 ("the Soerensen Patent Application"), as well as US Patent No. 4,212,889 ("the Fuentevilla Patent"). I have also reviewed the Final Office Action and the pending claims in the Soerensen Patent Application. Upon review of this material, I find that the Fuentevilla Patent does not disclose or suggest the invention set forth in independent claims 1 and 74 of the Soerensen Patent Application.
5. For example, claims 1 and 74 recite "the "hydrolysis area" and "inactivation area" operate in a continuous non-batch mode."
6. In the field of process chemistry, the term batch mode means a process in which substrates and catalysts are added to a vessel and the vessel is then closed to any further addition of reactants. The reaction is then carried out to completion and the products are removed. On the other hand, a continuous process is a process in which reactants and catalysts are continuously added while the reaction is on-going and the product is continuously removed.
7. The Fuentevilla Patent discloses a batch mode. Even though the Fuentevilla Patent uses the word "continuous" in the description, it describes a batch mode process. In process chemistry one differentiates between a sequential series of batch steps and a continuous process. The description and the claims in the Fuentevilla Patent clearly describe a sequentially run batch hydrolysis and inactivation, but Fuentivilla Patent mistakenly defines this sequence of steps as "continuous". As can be seen in the Fuentevilla Patent, for example, from Figure 1A, the hydrolysis and inactivation reactions are carried out in a closed reaction and without the continuous removal of products. In contrast, claims 1 and 74 of the Soerensen Patent Application recite a "hydrolysis area" and an "inactivation area" that "operate in a continuous non-batch mode." Accordingly, the Fuentevilla Patent mistakenly labels a "sequential" batch process as a "continuous" process.

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8. Accordingly, the Fuentevilla Patent does not disclose the invention of claims 1 and 74 of the Soerensen Patent Application.
9. Moreover, the Fuentevilla Patent does not suggest or teach a "hydrolysis area" or an "inactivation area" that "operate in a continuous non-batch mode" of claims 1 and 74.
10. First, due to a number of technical difficulties, one would not be motivated to convert a batch process into a continuous process for the production of protein hydrolysate. For example, in the art, batch hydrolysis of protein raw material is a preferred means to control hydrolysis parameters such as temperature, duration of hydrolysis and amount of enzyme. This is especially so where the properties of the raw material to be processed are inconsistent. Compared to batch mode, the control of hydrolysis parameters in a continuous process requires tackling a number of technical problems. To determine reaction parameters (for example, the rate of movement of the reactants through the reactor (residence time or reaction time), the temperature of the reactants, the amount of the enzyme and the quantity of substrate) is significantly more difficult in a continuous hydrolysis process versus a batch process.
11. Second, there are certain problems that would discourage one from trying to convert a batch process, as described in the Fuentevilla Patent, into the continuous non-batch process of claims 1 and 74. For example, the problem of solid or semisolid material clogging due to the increased flow-through demands of a continuous mode would discourage one from trying such a conversion.
12. Third, the quality of the final product produced by the continuous process of claims 1 and 74 is unexpectedly superior to that of a batch process. In protein hydrolysis process, underhydrolysis of the raw materials is a common cause of inferior product. In a batch process, the enzyme kinetics are such that the amide bonds against which that enzyme has the highest activity are often "over" cleaved, whereas the amide bonds for which the enzyme has lower activity are often "under" cleaved. This results in a product that

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contains a mixture of peptides with an often undesirable variation in size. In a batch process reducing such a variation in size is often unattainable. In a continuous process however, two different enzymes, having different affinities for the substrate, can be used at different locations in the continuous line. This results in a superior product with a narrow peptide size range and more normally distributed amino acid selection in each peptide.

13. I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements, and the like so made are punishable by fine or imprisonment, or both, under Section 1001, Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 12 February 2008

By: Bomi Patel Framroze
DR. BOMI FRAMROZE